March 23, 2012 Email

Exhibit 161

From: Chartier, Frank D. \(CMS/CPI\)
To: Christopher Mucke
Cc: Schultz, Theresa A. \(CMS/OAGM\); Sanders, Jessica B. \(CMS/OAGM\)
Subject: 2007 Excluded Providers
Date: Friday, March 23, 2012 4:01:54 PM

Mr. Mucke,

CMS requests that ACLR submit 2007 excluded provider improper payment findings and recalculated reconciliations to Livanta and CMS no later than April 16th. Findings are limited to prescribing providers and servicing providers (pharmacies) that share a direct link to the excluded provider database. A direct link constitutes a PDE field reflecting an ID that has been identified as excluded in the OIG database. Instances where an excluded pharmacist is working for, or an owner of, a pharmacy, should not be considered excluded for the scope of this review.

Thanks,

Frank D. Chartier

Centers for Medicare & Medicaid Services
Center for Program Integrity
Division of Plan Oversight and Accountability
7500 Security Blvd.
Baltimore, MD 21244
Location: AR-15-11
Mailstop: AR-18-50
T - (410) 786-8075
Frank.Chartier@cms.hhs.gov

Part D RAC, Modification 8

Exhibit 162

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
000008	See Block 16C	N/A	

6. ISSUED BY — CODE ASG - DPIFMC

CMS,OAGM,ASG,DPIFMC
7500 SECURITY BLVD., MS: C2-21-15
BALTIMORE MD 21244-1850

7. ADMINISTERED BY (If other than Item 6) — CODE AGG/JM

Justin Menefee
Contract Specialist

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

ACLR, LLC
Attn: CHRIS MUCKE
550 FOREST AVENUE
SUITE 15-2
PLYMOUTH MI 481703793

CODE 780272873 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MODIFICATION OF CONTRACT/ORDER NO.
GS-23F-0074W
HHSM-500-2011-00006G

10B. DATED (SEE ITEM 13)
01/13/2011

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
N/A

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	FAR 43.103 (a) Bilateral Modification
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 20-2662374
DUNS Number: 780272873
The purpose of this modification is to:

1)Authorize ACLR to conduct 2009 duplicate payment reviews for the following three plans:

- Windsor Health
- Wellcare
- Humana Insurance Company

End of Modification.
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
G.P. MUCKE ACLR COMPLIANCE OFFICER	Nicole Hoey
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED 7/15/15
16B. UNITED STATES OF AMERICA (Signature of Contracting Officer)	16C. DATE SIGNED

NSN 7540-01-152-8070
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

Excerpts from the (30)(b)(6) Deposition of Christopher Mucke in ACLR I

Exhibit 163

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

ACLR, LLC,	:	
Plaintiff,	:	
v.	:	Civil Action No.
UNITED STATES OF AMERICA,	:	15-767C
Defendant.	:	

30(b)(6) Deposition of CHRISTOPHER MUCKE, a witness herein, at the law offices of David, Brody & Dondershine, LLP, 12355 Sunrise Valley Drive, Suite 650, Reston, Virginia, commencing at 8:55 a.m. on Tuesday, November 7, 2017 and the proceedings being taken down by stenotype and transcribed by Catherine B. Crump, a Notary Public in and for the Commonwealth of Virginia.

Q. And then above that, Gil Mucke had responded on the same date stating that ACLR was not available to perform this type of work until our return on 11-24. Do you see that?

A. Yes.

Q. So why was that? Was the entire company shut down for those 10 or 11 days or why was that?

A. Actually, it was. It was hunting season. We have a lot of hunters.

In this case and, ultimately, we didn't wait that long. We got back and got them uploaded immediately, but when this first came out, the reason we had that is I was actually in a location where I had to travel to the top of a hill to make a phone call. So we didn't have lot of access to anything, really.

Q. That was a hunting trip, you were on?

A. Yes.

Q. At this point in time, who was involved in the duplicate payment audit issue process for ACLR? You, Gil Mucke, and Thais Thompson. Was anybody else involved?

2012, 2013?

A. This chart was merely meant to represent the amount of delays that not only occurred on the contract, but were continuing to occur. I didn't really relate it at all to any part of the amounts that we claimed for those periods, for the '12-'13 period.

[ACLR Exhibit No. 42 was marked for identification.]

BY MR. PORADA:

Q. Exhibit 42 that you have in front of you, PY 07 Duplicate Payments, 12-07-11 D.P. Improper Payments, ACLR Protocol, this is something else that came with your certified claim; is that correct?

A. Yes.

Q. And who prepared this table?

A. I did.

Q. This table wasn't actually submitted to CMS on 12-7-11; this came with your certified claim; is that correct?

A. That's correct.

Q. So was the first time that this

information was provided to CMS in connection with the Payment Year 07 duplicate payment issue?

A. I don't know. Again, it may have been submitted in our duplicate payment audit findings previously. In fact, I think this claim was in March of 2015 and we had actually -- I think we had done that duplicate payment claim shortly thereafter, but I'm not really sure.

Yes. The pending one on Exhibit 36.

Q. So you're saying this table, Exhibit 42, might have been provided to CMS in connection with the Part D RAC Report of Findings on the duplicate payment issue, Exhibit 36?

A. Yes. I'm not sure though. Maybe it was just the amount, but I thought that there was a table attached to that report, but there may not have been.

Q. And the Exhibit 36, the Part D RAC Draft Report of Findings, that was submitted to CMS sometime in 2015; is that correct?

A. I believe that's the case, yes. I'm not sure.

Q. So, either way, it sounds like what

you're saying is that this information, Exhibit 42, was not submitted to CMS prior to sometime in 2015 either as part of the certified claim or perhaps as part of that Part D RAC Draft Report of Findings, Exhibit 36; is that right?

A. You know, again, Mr. Porada, I'm not really sure. Under the original PWS, I wasn't required to submit anything to them, but, you know, we've had this data for a long time.

I can't recall if this information was shared with CMS in '12 and '13 when we were discussing -- or 2013 when we were discussing the duplicate payments. I know that our methodology came up in multiple conversation, but I do know that, yes, at this point in time, this is when we submitted the report to CMS.

Q. In 2015?

A. I know that it was submitted to CMS with our claim.

Q. Okay. And you don't remember, sitting here today, having actually submitted it at any point prior to 2015?

A. Well, again, you say submit. When I

think of submit, it's like a formal process. I may have shared it with them, but, again, under the PWS that was existing, you know, it was -- you know, I didn't submit.

Q. Okay. Let's use the word "share", then, if that's what you prefer. Do you recall sharing this table with CMS prior to 2015?

A. No. I don't recall it.

Q. And can you tell me what is this table reflecting or representing?

A. This was our calculation of the improper payments associated with our duplicate payment protocol for the duplicate payments we identified in 2011.

Q. For Payment Year 2007?

A. That's correct.

Q. So if you look at the last page, there's a total at the very bottom. That seems to be the same $313.8 million number that carries forward into your complaint as the amount of duplicate payments you believe you identified for 2007. Correct?

A. That's correct.

Q. So if I'm understanding this, this table is listing each contract of record in which ACLR identified any amount of what it believed were duplicate payments; is that right?

A. That's correct.

Q. And then it lists the total amount for each contract of the payments that ACLR believed were duplicates. Right?

A. That's correct.

Q. This table doesn't identify the specific PDEs; it's just the total amount for each contract that you believed were duplicative; is that correct?

A. That's correct, although, I believe in the claim itself, we submitted a CD, I believe, that all the PDEs were with it as well, but we did not print off the exception reports for that.

Q. So it's your belief that along with the certified claim, there was a CD that was submitted that had all of the PDEs for all of these $313.8 million for 2007 duplicate payments?

A. Well, not just that, but the totality of our claim. We included all of the evidence in there,

Revised Duplicate Payment Decision Notice

Exhibit 164

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

Revised Duplicate Payment Decision Notice

Date: May 6, 2014

Issue: Duplicate Payment

RAC recommended recovery audit type: Automated Review

Estimated Potential Recoveries: $4 million annually

Process Synopsis: The Part D Recovery Audit Contractor (RAC) has outlined steps to calculate improper payments associated with duplicate payments for Medicare Part D PDE records. The proposed review process consists of an exact match review, calculating days elapsed between matched records, and calculating allowable days elapsed to identify duplicative records.

During the exact match portion of the review the RAC will identify all PDE records where the contract, beneficiary, medication, and fill number match using the PTAP_CNTRT_OF_REC, PTAP_PBP_OF_REC, PTAP_INS_CLAIM_NUM, PTAP_PROD_SERVICE_ID, PTAP_FILL_NUM fields of the PDE. PDEs associated with partial fills are removed as well as duplicative records associated with long term care, vaccination administrative fees, and duplicates arising from the transition from a retail pharmacy to a mail order pharmacy are eliminated.

To calculate the elapsed days, a "Days Elapsed" field is created and populated as the difference between the PTAP_RX_DOS_DT fields of the original PDE record from that of the subsequent PDE record. Then an "Allowable Days Elapsed" field is created and is calculated by multiplying the days-supply field of the original PDE recorded by 50%. Once complete, PDE records where Days Elapsed is less than Allowable Days Elapsed are identified.

Decision Summary: CMS issued a conditional approval to the RAC on April 18, 2014. The RAC was required to modify the NAIRP to clearly define a duplicate payment, provide details for the 50% elapsed time approach, and provide the audit years and estimated recovery amounts. The RAC submitted a revised NAIRP on April 25, 2014 that addressed the requirements of the conditional approval. Based on further review and considerations, CMS believes the Duplicate Payment review should be a complex review due to the complexities of the fields that must be matched and the calculation of the elapsed time. This will help reduce the potential of including false positives in the improper payment amounts.

In conclusion, CMS is revising the conditional approval of the Duplicate Payment proposal with the following modifications:

- The RAC change the review from automated to complex

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

A Revised NAIRP must be submitted to CMS within 7 days for final approval after the RAC makes the appropriate modifications. Once CMS provides the final approval, the RAC should submit a draft of the Request for Information (RFI) and the associated PDE records to CMS for review prior to sending to plan sponsors.

January 21, 2015 Email

Exhibit 165

From: Gil Mucke
To: Christopher Mucke
Subject: FW: Discuss RAC Part D
Date: Wednesday, January 21, 2015 3:35:04 PM

They are missing some questions and also have not answered the specifics with delays and the DVC. In meeting will call

---

From: Menefee, Justin (CMS/OAGM)
Sent: 1/21/2015 3:27 PM
To: Gil Mucke
Cc: Hoey, Nicole E. (CMS/OAGM)
Subject: RE: Discuss RAC Part D

Good afternoon Gil,

CMS provided responses in red to the below questions:

Current Delayed Actions:

1) DEA Schedule Drugs (PY10-PY11) DVC review complete and results accepted by ACLR 05 November 2014. COR stated OGC approval of NIP letter is result of delay. (SOW Complex Review Step 5/6, Page 29 refers). NIP letter internal CMS approval processes are not defined in the SOW other than a 7 day requirement for RAC submission.
   OGC and CPI have submitted final comments. The letter is awaiting final management approval. CPI anticipates sending final to ACLR by COB, 1/23/15.
2) Duplicate Payments (PY11-PY12) originally held pending PDE re-validation with DVC. DVC received new PDE PY11-PY12 files 30 September 2014. COR placed RFI release on hold 12 September 2014. (SOW Complex Review Step 1, Page 29 refers). SOW does not articulate holding RAC release of RFI on approved NAIRP issues for associated Plan Years.
   As far as the SOW is concerned, the RAC must get each RFI approved before sending to the plan sponsors. CMS explained to ACLR in previous discussions that RFIs for the PY11 and 12 duplicate payment will be held until issues with PY10 are resolved. There have been significant issues raised by the plan sponsors, the DVC and CMS for the PY10 review. Until such time as these issues are resolved, CMS will not approve RFIs for the duplicate payment review for (PY11and 12).

Confirmation of Requested Prior Plan Year issue approval when PY13 PDE is received:

- Unauthorized Prescribers (PY13)
  When PY 13 data is received, ACLR should submit this to CMS as a new audit issue(one of their two per month submissions) which will not require full vetting through the approval process unless their methodology has changed.
- DEA Schedule Drugs (PY12-PY13)
  Same response as above

Upcoming DVC Deliverable Concern:

- PY10 Duplicate Payment IPRP submission 23 December 2014 with DVC IPRP review due 06 February 2015 (SOW Complex Review Step 4, Page 29 refers). DVC reviews have resulted in significant past delays and ACLR views with concern.
  The RAC had 30 days (deadline of 1/8/15) to complete its review of the RFI submissions and submit IPRPs to the DVC for the PY10 Duplicate Payment review. The DVC was not tasked with beginning its validation prior to 1/8/15. However, since the RAC submitted its

results over 2 weeks early, the DVC confirmed that they received the data and began performing a data discovery prior to initiating its validation. As a result of the data discovery, the DVC informed CMS that they needed specific information from the RAC in order to initiate the validation. The RAC has not provided the information. OAGM is currently reviewing this issue.

Please let me know if you have any questions or concerns.

Thank you,

Justin

From: Gil Mucke [mailto:gmucke@aclrsbs.com]
Sent: Wednesday, January 14, 2015 11:11 AM
To: Menefee, Justin (CMS/OAGM)
Cc: Hoey, Nicole E. (CMS/OAGM)
Subject: Re: Discuss RAC Part D

Justin, as addressed in our letter, the below actions have been held up from last year. We would like a response to each:

1. The RAC is prepared to send PY11-PY12 Duplicate Payment RFIs to plan sponsors in accordance with the approved NAIRP and SOW on January 23, 2015.

2. The RAC is prepared to send PY10-PY12 Expired Prescription RFIs to plan sponsors in accordance with the approved NAIRP and SOW on January 16, 2015.

3. Will CPI release the PY10-PY11 DEA Schedule NIP letter, originally due November 5, 2014, for RAC generation and submit the NIP letters to plan sponsors no later than January 23, 2015?

These are the only points/questions we have for the call. Thanks, Gil.

From: Menefee, Justin (CMS/OAGM) <Justin.Menefee@cms.hhs.gov>
Sent: Wednesday, January 14, 2015 7:48 AM
To: Brown, Sonja J. (CMS/CPI); Kenya, Dominca (CMS/CPI); Schultz, Theresa A. (CMS/OAGM); Hoey, Nicole E. (CMS/OAGM); Harris, Monique (CMS/CPI); Scott, Jamie (CMS/CPI); Gil Mucke; Mucke, Gilbert P. CDR (CVN78) (Gilbert.Mucke@cvn78.navy.mil)
Subject: Discuss RAC Part D
When: Wednesday, January 14, 2015 2:00 PM-3:00 PM.
Where: Teleconference

Agenda items are below:

January 15, 2015 Email

Exhibit 166

From: Gil Mucke
To: Hoey, Nicole E. (CMS/OAGM)
Cc: "Menefee, Justin (CMS/OAGM)"
Subject: Requested response to the January 14,2015 Conference Call
Date: Thursday, January 15, 2015 8:44:00 PM
Attachments: RE DVC Validation Results (Revised Duplicate).msg
12.23.14 PY10 DP Findings Letter to COR.pdf

Nicole,

Per your request during our phone call January 14, 2015, the following is provided.

CORs actions related to the revised protocol for PY10 Duplicate Payments:

The COR statement that the approved SOW Section 2.1.2 Improper Payment Impact Calculation Methodology provides direct authority without OAGM involvement to revise an approved NAIRP is without merit. As ACLR worked with CMS to design the Impact Calculation Methodology, we are fully aware of the relationship of this section in the SOW. To be specific, the referenced Appendix D in the SOW, states, "The purpose of this appendix is to outline the methodology the RAC, as advised by CMS, should use to calculate the impact of any improper payments found as a result of *auditing the approved issues*." The appendix fully defines this methodology and any application to revising an approved NAIRP would have been challenged if addressed previously by the COR.

The COR also disputed my discussion related to our position that these actions are contract changes and the RAC would proceed with the review under the approved NAIRP. As I stated, on the November 14, 2014 conference call, the COR specifically stated she knew this was a contract change and we did not need to have any more discussions on it. I also stated that in a phone conversation on December 4, 2014 that I specifically stated to her that ACLR would perform this review in accordance with the approved NAIRP. While this is a challenge for OAGM to interpret unrecorded conversations, I would reference one more statement the COR made when she asked if there was anything in writing. The attached email has a statement from me on the date of the conference call that specifically states, "As discussed last week, we spent significant resources to perform the new protocol on a released RFI "outside of contractual processes" within the short time frame requested. As the DVC is not "contractually" part of the RFI process, the choice to use the DVC was solely CMS and, as I stated to you last week, we are not available to perform this type of work until our return 11/24." For clarity, the term "everyone" and "we" and not inclusive of ACLR. As there are many emails of frustration from ACLR during this time period, the easier answer is if the COR knowing that the contractor deems her actions to be outside the scope of the SOW has the authority to proceed without OAGM involvement.

Duplicate Payments NAIRP:

As not to overload this email, ACLR's protocol for this review was rejected and changed by CMS in March 2012. We performed a special study on the protocol under Modification 8 in 2013 in which we were not allowed to recover the improper payments. During the RFI release, the COR had the DVC review the RFI outside of contractual processes and they brought up the issue of dosage changes and we disputed and CMS agreed to the protocol as written (based on special study

results). After RFI release and pressure from industry, CMS requested the DVC to find a way to reduce the PDE and the result was the same dosage implication that CMS previously rejected. As these are all formal reports, they are available on request. As a matter of some relief, the plans now argue that the original protocol designed by ACLR is more reflective of Duplicate Payments. While we agreed with the plans in the review report attached, the plans are also required to provide evidence when directed and absent that evidence, the PDEs are determined to be improper. As we submit, the records should be reviewed based on evidence without protocol modifications.

ACLR's Request from OAGM:

As the Duplicate Payment issue took considerable time during the call, ACLR still request response to our letter and the questions submitted during the call. As stated in the call, we have experienced significant delays related to our COR and related actions of CMS CPI that are all contained within our monthly reports and associated calendars. For a contract in the last Option Year, the delays since inception of our contract have totaled 207 days in 2012, 321 days in 2013 and 603 days in 2014 and this trend without accountability to the contracted timelines requires ACLR to reassess the value of proceeding. As discussed with Justin during our push to get CMS CPI to update the SOW, we intend to execute the SOW as written and any other interpretation that provides CMS CPI unilateral authority to make internal decisions to delay deliverables, modify processes, or otherwise create actions to reduce approved improper payments prevents us from achieving the fruits of our contract. As Theresa stated in April 2014, OAGM has no ability or intent to provide additional relief or other dispute avenues. The results of your decision and related findings to our questions are significant and we request a clarity in the response that has the full enforcement of OAGM so we might adequately assess.

Thank you for your time,

Gil Mucke
ACLR Contract Compliance Officer

From: Brown, Sonja J. (CMS/CPI)
To: Gil Mucke; Thais Thompson
Cc: Christopher Mucke; Harris, Monique (CMS/CPI); Kenya, Dominca (CMS/CPI); Newkirk, Delois J. (CMS/CPI); Tetkoski, Frank (CMS/CPI); Thomas, India M. (CMS/CPI)
Subject: RE: DVC Validation Results (Revised Duplicate)
Date: Friday, November 14, 2014 6:43:32 AM

Gil and Chris,
When we initially spoke about the need to revise the protocol and produce new exception reports for the plan sponsors, EVERYONE was well aware that it was not part of the contractual process for the RAC or the DVC; however, in an effort to alleviate the plans from having to respond to any false positives, EVERYONE agreed to the process in which the RAC would rerun the exception reports, the DVC would validate the reports and the RAC would review the DVC's results and respond accordingly. Additionally, CMS made it clear from the beginning that this process had to happen within a shortened time frame in order to get the revised reports to the plans well before the 12/8 deadline. That shortened time frame did not include the normal 45 day validation period or the 7 day dispute period. It was always CMS' understanding that the RAC could and would comply with all phases of the process, regardless of the scheduled vacation as RAC operations are expected to continue. It is unreasonable to expect CMS to wait until your return to resolve this matter.

Since the RAC has made the decision to dispute all of the DVC's findings and will not be avaliable to discuss the discepancies or make any necessary changes, the process has been stalled. It would be irresponsible for CMS to move forward with the RAC's exception reports with so many outstanding discrepancies and risk our credibility with the plans. As such, your response will be noted and forwarded to management for next steps.

Thanks,
Sonja

-------- Original message --------
From: Gil Mucke <gmucke@aclrsbs.com>
Date:11/13/2014 9:55 PM (GMT-05:00)
To: "Brown, Sonja J. (CMS/CPI)" <sonja.brown@cms.hhs.gov>, Thais Thompson <tthompson@aclrsbs.com>
Cc: Christopher Mucke <cmucke@aclrsbs.com>, "Harris, Monique (CMS/CPI)" <Monique.Harris@cms.hhs.gov>, "Kenya, Dominca (CMS/CPI)" <Dominca.Kenya@cms.hhs.gov>, "Newkirk, Delois J. (CMS/CPI)" <Delois.Newkirk@cms.hhs.gov>, "Tetkoski, Frank (CMS/CPI)" <Frank.Tetkoski@cms.hhs.gov>, "Thomas, India M. (CMS/CPI)" <India.Thomas@cms.hhs.gov>
Subject: Re: DVC Validation Results (Revised Duplicate)

Sonja,

As discussed last week, we spent significant resources to perform the new protocol on a released RFI "outside of contractual processes" within the short time frame requested. As the DVC is not "contractually" part of the RFI process, the choice to use the DVC was solely CMS and, as I stated to

you last week, we are not available to perform this type of work until our return 11/24.

If we were to assume this is part of the automated review process and we are in the 7 day discussion period with the DVC, the below would be our comments based on the documents we were able to review:

- Dosage change – 2,011 PDE pairs - The DVC's findings were in error. PDE selected did not meet 150% protocol discussed during call. (As you may recall, this requirement was implemented to address the revised protocol's assumption that a duplicative dispensing event was not deemed a 100% increase.)
- Missing Contract – 245 PDE pairs – We cannot address this finding, this contract was included in our original review and submitted to the plan in the original RFI.
- Different Pharmacy – 121 PDE pairs – The DVC's findings are in error. In every case we reviewed, these PDE were associated with multiple duplicative records (triple, quadruple, etc). For example, the first and second PDE matched on pharmacy and were within 150% protocol. The second and third PDE didn't match on same pharmacy but were same date of service; also within the protocol. (DVC matched third to first).
- LTC – 3,145 PDE pairs; The DVC findings were in error. The DVC did not follow approved NAIRP - selected NPI numbers were not listed in CMS' IDR database as required in the NAIRP. As discussed extensively during the NAIRP approval process in reference to determining the NPIs for Long Term Care pharmacies, the RAC was forbidden by CMS to utilize external resources. Specifically, the RAC was instructed, and the approved NAIRP required, that only those NPIs contained within CMS' IDR be utilized - we were unable to match any DVC NPIs to this database and the DVC is using it on a protocol rerun that did not even mention LTC. Additionally, validating a last minute protocol change from a quality control perspective should not include those things outside of the protocol. If CMS so directed, the RAC should have had same direction. If not, the DVC should be directed to follow approved protocols.
- P2P – 2,492 PDE pairs. The DVC's findings were in error. The DVC did not follow approved NAIRP — selected PDE did not account for another matched record which was not a P2P record.
- Unpaired Records – 10,568/ PDE pairs – The DVC's findings were in error. We were able to pair each record we reviewed. If DVC is unable to perform the review within tight time constraints, then removal of a record should not be dictated.

If CMS wants to hold this off so that we may adequately dispute each and every finding with the DVC, we intend to do so. As we stated last week, if CMS' goal is to get the plans relief...then we recommend the exception reports provided by the RAC be immediately forwarded to the plan sponsors for consideration. Again, these issues related to the DVC are better solved during NIP submission where they reside in the process. Otherwise, we can address outstanding issues upon our return.

From: Brown, Sonja J. (CMS/CPI) <sonja.brown@cms.hhs.gov>

Sent: Thursday, November 13, 2014 12:04 PM
To: Gil Mucke; Thais Thompson
Cc: Christopher Mucke; Harris, Monique (CMS/CPI); Kenya, Dominca (CMS/CPI); Newkirk, Delois J. (CMS/CPI); Tetkoski, Frank (CMS/CPI); Thomas, India M. (CMS/CPI)
Subject: DVC Validation Results (Revised Duplicate)

Good Afternoon Gil and Thais,
The DVC has completed its validation of the revised exception reports for the duplicate payment review. The results can be found in the following location: PARTDRAC ▶ Duplicate Payments ▶ DVC Validation Results (Revised Duplicate RFI). If you are in agreement with the results, please make the necessary changes by 12pm on 11/14 so that we can move forward with getting the revised RFIs out the door. If you will have an issue meeting the proposed deadline, let us know right away.

Thanks,

Sonja J. Brown
Centers for Medicare & Medicaid Services
Center for Program Integrity
Investigations and Audits Group
Division of Plan Oversight and Accountability
410-786-3571 (Office)
Sonja.Brown@cms.hhs.gov

ACLR

28705 Seven Mile Rd.
Suite 251
Livonia, Michigan 48152
Ph: 734.744.1100 Fax: 734.744.1150

December 23, 2014

Sonja Brown
Contracting Officer's Representative; CMS CPI
7S00 Security Boulevard
Baltimore, Maryland 21244-18S0

Re: PY10 Duplicate Payment Review - IPRP Submission

Dear Ms. Brown:

We have completed our review of all PDEs and RFI submissions pertaining to the PY10 duplicate payment review. Our IPRP submissions and a discussion of our findings are outlined below.

IPRP SUBMISSIONS:

Exception Reports:

As we explained to CPI personnel earlier, the PY10 Duplicate Payment audit commenced prior to the implementation of PRIS. Because of this, the unique PDE identifiers submitted to plans via the RFI are different than those utilized by PRIS. As we were unable to resolve whether the PRIS or RFI identifier should be utilized, we made two IPRP submissions. The first via PRIS and the second via QuickR.

The PRIS submission is in accordance with SOW requirements. The "QuickR" submission utilizes the RFI identifier and may be found in the Duplicate Payment 122214 folder. In this manner, CMS can review the issue more closely and determine which process to utilize without further RAC efforts. Please note that it will be necessary to inform the DVC of the identifier issue should CMS choose to the PRIS submission. Most of the plans submitted their documentation utilizing the RFI identifier and it will be necessary for the DVC to regenerate the reports (using the PDE databases submitted to them earlier this year) utilizing the PDE identifiers we sent the plans earlier this year.

RFI Responses:

As previously discussed in our request/recommendation for the use of a sFTP for RFI submissions, CMS security requirements, evidentiary responses, and file size restrictions preclude a submission via PRIS. As CMS' decision to utilize a sFTP is pending, we shipped an encrypted hard drive containing evidentiary support submitted by the plans to the DVC as was done for the previous DEA Schedule complex review. The DVC's password was emailed separately to DVC Project Manager Chris Mendez. In the event that CMS wants access to the evidence as well, please inform the DVC and request that the encrypted drive be forwarded to you for download. CMS' password to unlock the data is 106238490710 (this code is unique to CMS). Please return the hard drive as soon as possible once you have downloaded/reviewed its contents.

REVIEW PROTOCOL:

An overview of the review protocols utilized by ACLR during this review are summarized below:

Review Considerations:

- Each prescription must be validly written;
- Review screen prints for additional information not already contained in the PDE record that may support the legitimacy of the duplicative PDE (e.g. Rx Written Date);
- Verify internal controls are consistent throughout SO contentions. For example, one plan contended that all changes in dosage were identify PDE was accompanied by Prior Authorization Code "DC" and should not be considered duplicative. The same plan also submitted documentation noting many dosage changes occurred as a result of day supply and quantity dispensed calculations; the Prior Authorization Code for each of the records submitted; however, was blank;
- Plan Sponsors are legally and contractually required to submit requested documentation; the failure to [sufficiently] provide such documentation results in an improper payment determination;
- CMS requires that plan sponsors "accurately" report all PDE fields. In addition, federal and state law requires that key dispensing event fields such as patient and prescriber information, drug name, days supply, SRN, quantity dispensed, date of service, and fill number be accurately and uniformly documented; any such errors to the PDE/EMR (electronic medical record) results in an improper payment determination.

Acceptable Documentation:

- Valid prescription copies for both original and duplicate PDE;
- Valid prescription copy for duplicate PDE so long as the date does not precede the original PDE DOS;
- Screen prints for Duplicate PDE containing notations indicating legitimate override (e.g. "Patient indicated child flushed medication down toilet"); and
- Screen prints for both original and duplicate PDE containing an "Rx Written Date" for the duplicate record which is subsequent to the original PDE "Date of Service".

Automatic Overrides:

- The Date of Service for both the original and duplicate PDE records is the same;
- RFI submissions indicating the authorization of an early refill and the prescription is not the result of a Federal Disaster override; and
- RFI submissions indicating a dosage change where the Fill Number is not equal to zero.

REVIEW RESULTS:

Overview:

Of the 367 plans that received an RFI, 254 plans submitted evidence for an average of 29% of the original documents requested. Of the remaining plans, 53 plans did not respond to the RFI and 60 plans

submitted a spreadsheet with no additional evidentiary support. As documented in the IPRPs, we submitted findings for 294 plans in amounts totaling $15.9 million.

Evidentiary Findings:

The following chart summarizes the top five plan contentions. These percentages are based on only those records for which evidence was submitted[1].

Plan Sponsor Contention	%
90 Day Fills	11.32%
Dosage Change	17.41%
Not a Duplicate	31.05%
Pharmacy Override	8.99%
Prior Authorization	8.80%

Generally, we received no additional information related to "90 Day Fills" but some plans indicated that these were the result of retail pharmacies filling prescriptions in a manner similar to that of a mail order company. The most common plan assertion was "Not a Duplicate". This assertion was typically preceded by the words "there was a different service reference number" with no additional evidentiary support. Similarly, pharmacy overrides and prior authorization assertions were not fully documented or were accompanied by notes such as "Tina authorized this override". In each instance, we reviewed RFI submissions in accordance with the protocols outlined in *Review Protocol* above[2].

Protocol Findings:

As we noted in our ESI Assertions - Duplicate Payment RAC Audit response letter to you dated September 2, 2014; CMS published a duplicate payment protocol in March 2012, which identified duplicates where multiple PDEs with matching beneficiary, drug, and fill numbers matched on or close to the same date of service. It was this protocol that was utilized during the 2013 special study and upon which the Duplicate Payment NAIRP was based and our IPRP submission is based. The primary concern voiced by plan sponsors regarding the use of this protocol during this review was the decision to eliminate the Service Reference Number SRN as a determinative factor in identifying individual prescriptions; we share these concerns. As we discussed during the NAIRP review process, CMS' *Requirements for Submitting Prescription Drug Event Data, Memo to Plan Sponsors issued April 27, 2006* states "in the majority of cases, the concatenation of Service Provider, Prescription/Service Reference Number and Fill Number uniquely identify a prescription"[3]. Our review of RFI responses supports this contention. For example, one significant finding was that plan sponsors deleted 84% of all PDE associated with matching SRNs[4] versus 1.3% of those PDE which did not[5]. In addition, we also

[1] These findings are based on individual and unaudited RAC observations and are intended for informational purposes only.
[2] At one point, CMS requested that we perform a calculation to eliminate potential false positives arising from legitimate dosage changes. Plan RFI submissions indicate; however, that this protocol would have only been accurate in 26.7% of identified cases.
[3] The concatenation of Service Provider and Prescription/Service Reference Number uniquely identify a prescription while the addition of the fill number identifies unique prescription drug events.
[4] There were 23,632 pairs identified in this protocol which contained a matching Prescription/Service Reference Number.

conducted a review of all PY10 PDE data, which is comprised of 1,101,783,133 PDE. Of these data, we noted 8,SS7,849 PDEs that were comprised of matching SRNs, beneficiary, drug, and fill numbers. Another significant finding arose, when we compared our findings for the NAIRP (non-matching SRN) to PDE with matching SRNs, beneficiary, drug, and fill numbers. In this case, we noted that only 37,870 duplicative PDEs for Kaiser, a plan sponsor we noted as having strong internal controls in previous audits, would have been identified versus the 126,629 potentially duplicative PDE identified as a result of this protocol.

For these reasons, we will recommend that CMS determine duplicate payments by concatenating the Service Provider, SRN, beneficiary and fill number fields as an automated review in future audits of this issue. As outlined further under *CPI Consideration* below, we have also submitted for CMS' review, the use of this protocol for the PY10 Duplicate Payment audit currently under review.

CPI CONSIDERATION:

We recognize the need to follow approved NAIRP protocols, and have submitted IPRPs for this audit accordingly. We also believe; however, that audits are fluid in nature and should be adaptive to observations made during the audit. As outlined under *Review Results - Protocol Findings* above, it is clear that matching the SRN is instrumental in determining individual prescriptions. This is supported by plan contentions in its RFI submissions, PY10 PDE data demonstrating that individual SRNs are submitted in 99.22% of all PDE submissions, and that findings for plan sponsors more accurately reflect the strength of individual internal controls identified in previous reviews.

For these reasons, we also determined duplicate payments arising from the concatenation of the Service Provider, SRN, beneficiary, and fill number fields as discussed above. In addition to eliminating any plan sponsor or internal CMS concerns pertaining to the identification of false positives arising from not using the SRN as a determining factor in identifying unique prescriptions, federal and state law requires that unique SRNs be applied to each prescription. As such, we believe the use of this protocol more accurately depicts duplicate payments occurring in PY10. Improper payments arising from this protocol total $161,989,261. We can submit IPRPs utilizing this protocol immediately upon CPI direction.

In summary, we have concluded our review of RFI submissions and fulfilled all SOW requirements related to the submission of our findings. Unless CPI directs us to submit IPRPs in accordance with the recommendation outlined above, all further RAC efforts regarding this review are held in abeyance pending the submission of DVC findings. We will of course make ourselves available to the DVC to discuss matters pertaining to our submission.

Very respectfully,

Christopher A. Mucke
Managing Director

[5] No or insufficient documentation comprised the remaining 16%.

cc: Thompson, Thais; Project Manager
Mucke, Gil; Contract Compliance Manager

January 17, 2012 Email

Exhibit 167

From: Christopher Mucke
To: Sanders, Jessica B. \(CMS/OAGM\)
Cc: Wheeler, Desiree Y. \(CMS/OAGM\); Gil Mucke
Subject: Part D RAC - Draft SOW Proposal - ACLR Counter
Date: Tuesday, January 17, 2012 11:14:00 AM
Attachments: Draft SOW Proposal Summary v1.pptx

Jessica, here is the summary for our proposal on the Draft SOW I will discuss tomorrow. Some elements of this may change as I am still working out the details. Please let me know if you have any questions.

Christopher Mucke | Managing Principal | ACLR, LLC
38705 7 Mile Rd. Ste 460 | Livonia, Michigan 48152-3975 | ☎(734) 744 - 4401 | 🖷(734) 744 - 4150 |
mailto:cmucke@aclrsbs.com

Revised SOW Proposal - Summary:

"Demonstration Audit"

- Audit Plan Year - 2007
- Audit Issue - Excluded Providers
- Standard CMS Recoupment Notification Letter to Plan Sponsors - February 13, 2012
- Recoupment - March 2012 Payment

1st Audit Cycle:

- Audit Plan Years - 2008/2009
- Audit (Non-RFI) Issues - 5 (DVC/CMS Review)
- Notification Letter via 2011 Final Reconciliation Payment Process - October 2012
- Recoupment - November 2012 Payment

SOW & Subsequent Audit Cycles:

- DIR Audits to Commence November 2012
- Bi-Annual Recoupment of RAC Audits
- Identify/Approve 10 -15 Audit Issues per Year
- Finalize DIR & RFI Audit Processes by August 31, 2012
- Finalize 5 Audit Issues in 1st Audit Cycle by March 30, 2012

Utilize Existing Law & CMS Processes
Mitigate Plan Sponsor Impact & Administrative Burden

ACLR Response to DVC Duplicate Payment RFI Report

Exhibit 168

ACLR

DVC Duplicate Payment RFI Report

ACLR Response

Report Date: June 26, 2014

ACLR Response Date: June 27, 2014

Issue: Duplicate Payment Review – DVC Validation

The following is our response to the four DVC observations as noted in its Duplicate Payments RFI Report dated June 26, 2014.

Terminated Contracts: Section 1.2.3 PART D CONTRACTS EXCLUDED FROM RAC REQUIREMENTS identifies PDE records that are Unavailable for Review (UFR) as:

> **Terminated Contracts** - These contracts with plan sponsors have been contractually ended by CMS on a prior date and are no longer eligible for Part D claims payments.

As such, we have eliminated all contracts that have been terminated by CMS as of January 1, 2014.

Plan -to-Plan (P2P): We are aware of this issue and while previous modifications of our contract required its elimination from review, our current contract does not. We recognize this was an oversight in our contract and have implemented a process by which we submit P2P PDE in compliance with contracted terms and conditions, but remove (without protest) those same P2P transactions when subsequently identified by the DVC. We have identified this as an item to be included in the forthcoming contract modification to the current audit processes.

Non-Standard Format: We have conducted numerous cursory reviews related to non-standard format codes and agree with the DVC vulnerabilities could exist. As we indicated in our response to Question 24 in our response dated February 27, 2014 to a related question in CMS' initial feedback, originally submitted by CMS on February 19, 2013, "we see a much higher percentage of likely duplication when a paper record has been input than when not". We have not conducted a review related to the "significant decline in 2012" but agree with the DVC that this is also indicative of potential weaknesses. As we have not received any information related to these claims; however, we cannot prove or disprove whether vulnerabilities exist for these records. We will; however, provide CMS with a report of our findings on this issue once evidence is submitted by the plans in accordance with the RFI.

Dosage Increase: As this issue was raised and thoroughly considered during the NAIRP submission, discussion, and approval process, we are unclear as to the additional information being requested. We were also unable to determine from the information provided, whether the DVC was submitting newly

considered evidence or revisiting evidence already submitted[1]. As such, we have limited our response to related discussions occurring during the NAIRP process.

We have been aware of this issue since the completion of the Duplicate Payment Special Study conducted on behalf of CMS and which was completed on or around August 29, 2013. As shown in the sample PDE data submitted with the NAIRP on January 2nd, 2014, and as detailed in plan responses to the special study there were numerous instances of "dosage change" PDE. As we discussed during the NAIRP approval process; however, it was unfortunate that the plans did not provide documentation supporting these assertions. As a practical matter, we believe that reliance on an unsupported "mathematical calculation" to determine legitimacy of any claim to be ill-advised. For example, it was plainly apparent from our review that the plans were performing multiple "mathematical calculations"[2] in an attempt to explain away selected PDE rather than conducting a review of objective evidence to determine the actual events leading to the duplication. As we discussed in our response to Question 13 of CMS' initial feedback to the Walkthrough Meeting, we addressed some of the issues associated with changes in dosage stating:

> To support its contentions, the plan stated the duplicative PDE were the result of their compliance with CMS guidelines and federal law ***by relaxing "refill edits"*** in major disaster areas. When reviewing the submitted data more closely; however, we noted that 581 of the "refills" had an original fill of "0" (indicative of a new prescription) and ***501 of the prescriptions were for a different dosage*** than the original fill amount (indicative of a level of care change). The plan also did not provide any supporting documentation or explanation as to why these "refills" occurred so quickly after the initial fill was completed. This was also supported ***by the plan's contentions that selected PDE were the result of "vacations", which also consisted of "different dosages"*** and identical fill numbers. [***Emphasis added.***]

Later in the response we noted:

> Further, the plan's contentions that a ***legitimate "dosage change" occurred*** was undermined ***when another field indicated that that the "same dosage" was administered.*** [***Emphasis added.***]

In the first instance, the plan contradicted itself in its response; either the PDE were related to a standard "early" refill permitted during disasters or a dosage change or the result of a vacation – multiple occurrences for the same PDE seem unlikely; the latter is self explanatory.

Again, it was immediately apparent upon reviewing the results of the Special Study that the plans were performing mathematical calculations to justify the duplicative events selected. In every instance the calculation was unsupported by verifiable evidence or later contradicted by another "mathematical calculation" or assertion made by the plan. It was our understanding that this was a primary reason behind CMS' ultimate decision to revise our originally proposed automated review to a complex review.

[1] *It was our understanding that the results of the special study had been forwarded to the DVC for review; please see our response to Question 2 in our memo dated February 27, 2014 where we responded "yes" to CMS' inquiry regarding DVC review of "100% of the results of the feasibility study".*

[2] *A similar calculation was used to calculate whether the duplicative PDE occurred within a 3 day period. If so, the plan noted it was an "e-box" claim.*

In summary, we agreed there may be instances where legitimate dosage changes may have occurred and supported CMS' decision to proceed with a complex review of this issue. As outlined in the RFI for this issue the plans will be required to:

> submit copies of the original, unaltered override documentation arising from loss, ***change in dosage***, other authorized override event; or other uniformly maintained readily retrievable record to demonstrate the legitimacy of the potentially duplicative PDE records listed in the RFI. [***Emphasis added.***]

In short, we will eliminate any PDE associated with an authorized "change in dosage" upon receipt of objective evidence indicative of same.

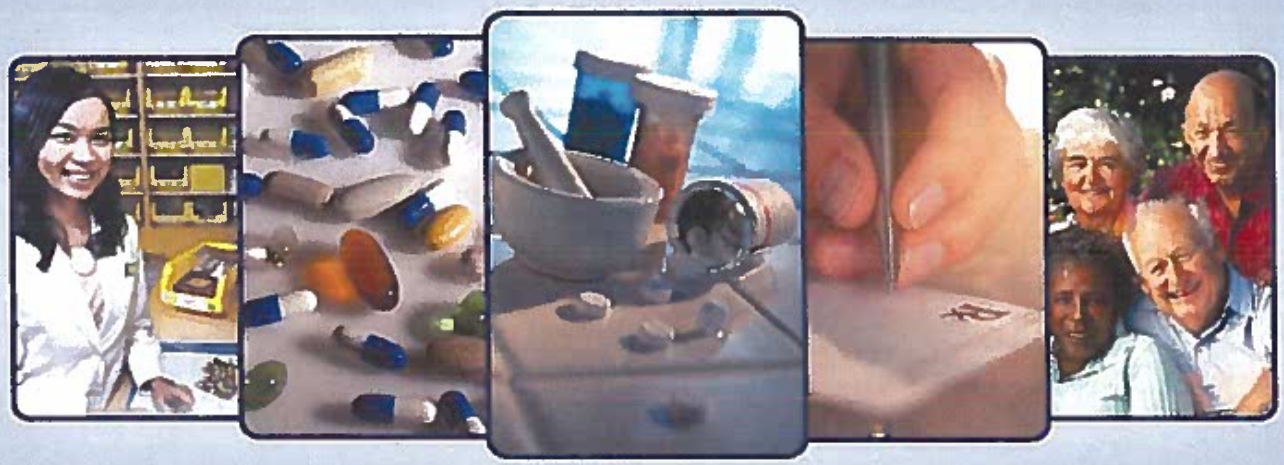
We agree with DVC assertions that the "quantity dispensed" field contains a "zero" for plan years 2011 and 2012 in numerous PDEs. As this is not a control field and the issue was not raised in the excluded provider and unauthorized prescriber audits, we conducted no additional reviews. As discussed on the call; however, we will review the original PDE submissions and provide CMS with additional feedback upon their completion.

Excerpts of 2011 Prescription Drug Event Participant Guide

Exhibit 169

CMS

CENTERS for MEDICARE & MEDICAID SERVICES



Prescription Drug Event Participant Guide

2011 Regional IT Technical Assistance

July 14 - 15, 2011 ◆ San Diego, California

INTRODUCTION

Purpose (Slide 2)

The purpose of this technical assistance session is to provide participants with the support needed to understand Part D payment and data submission. This information will enable participants to collect and submit Part D data in accordance with Centers for Medicare & Medicaid Services (CMS) requirements.

About This Technical Assistance Session

This session is organized into 12 modules:

1. **Part D Payment Methodology**
   Defines the Part D Prescription Drug payment calculation methodology based on the four legislated mechanisms.
2. **PDE Process Overview**
   Introduces key concepts associated with Prescription Drug Event (PDE) data, including collection, submission, formatting, editing, and processing.
3. **Data Format**
   Identifies the file layout for the PDE record and the formatting requirements for PDE fields.
4. **Calculating and Reporting the Basic Benefits**
   Provides an overview of PDE data submission for administration of the Part D Basic Benefit and Tiered Cost-Sharing.
5. **Calculating and Reporting True Out-of-Pocket (TrOOP) Costs & Reporting the Benefit Phases**
   Explains the process and requirements related to administering the TrOOP component of the Part D benefit.
6. **Calculating and Reporting Low Income Cost-Sharing Subsidy (LICS)**
   Describes the LICS and the process for calculating and reporting LICS amounts via PDE record submissions.
7. **Calculating and Reporting Enhanced Alternative (EA) Benefit**
   Provides the description of the EA benefit and essential reporting rules related to submitting data, including beneficiaries eligible for LICS.
8. **Edits**
   Interprets the edit logic for the Prescription Drug Front-End System (PDFS) and the Drug Data Processing System (DDPS).
9. **Reports**
   Provides an understanding of the way management reports can ensure both quality and quantity of data stored in the system.
10. **Coverage Gap Discount Program (CGDP) Invoice & Payment Process**
    Explains the invoice and payment process and reporting and reconciliation of the CGDP.
11. **Reconciliation**
    Explains the systems and steps for calculating components used in the reconciliation process.

ICON KEY	
Definition	
Example	
Reminder	
Resource	

1.2.1 Covered Drugs (Slide 5)

The four payment methodologies only apply to covered drugs. The term covered drugs refers to Part D drugs that a plan covers under its basic benefit. Covered drugs are Part D drugs approved for coverage under a specific Plan Benefit Package (PBP) or under exceptions, transitions, grievances, appeals, or other coverage determination processes. A Part D drug is defined as:

> Any prescription drug described in §1927(k)(2)(A) of the Act, a vaccine licensed under section 351 of the Public Health Service Act, a biological product described in §1927(k)(2)(B) of the Act, or insulin described in §1927(k)(2)(C) and medical supplies associated with the injection of insulin as allowed under §1860D-2(e)(1)(B). Except for smoking cessation drugs, Part D drugs must be prescribed for the purposes allowed under §1862(a) and §1927(d)(2) (e.g., reasonable and necessary guidelines, exclusion of drug classes used for weight loss or cosmetic surgery). Drugs cannot be billed as Part D drugs if they are already covered under Medicare Parts A or B as prescribed, dispensed, or administered (§1860D-2(e)(2)(B)).
>
> Applicable drugs may be covered under Part D only if the manufacturer has a signed agreement with CMS to provide the discount on coverage gap claims for all of its applicable drugs and remains compliant with the terms of that agreement.

1.2.1.1 Applicable and Non-Applicable Drugs

The Affordable Care Act identifies covered drugs as applicable drugs and generic drugs. Applicable drugs are drugs that are eligible for discount under the Coverage Gap Discount program. Generic drugs are non-applicable covered drugs that are eligible for generic cost-sharing in the Coverage Gap. Sections 1.4,1 and 1.4.2 provide more information on applicable drugs and generic drugs.

1.2.2 Gross Covered Drug Cost (Slide 6)

This and subsequent modules delineate specific rules plans must follow to report the prescription drug cost and payment amounts for covered drugs on the PDE record under all types of PBPs. This training also describes how CMS then uses those amounts to determine allowable costs for reinsurance and risk corridor payment and to pay the low income cost-sharing subsidy.

For two reasons, the drug cost reported on a PDE record must be net of plan administrative costs and net of any point of sale (POS) price concessions:

1. Part D payment is based on a subset of the reported cost that must be net of these amounts; and
2. Beneficiary cost-sharing is determined as a portion of the cost net of these two amounts.

Applicable and Generic Drugs

The Affordable Care Act defines applicable drugs and, as amended by the Health Care and Education Reconciliation Act of 2010, describes the provisions regarding coverage for generic drugs in the coverage gap.

Applicable drugs are Part D covered drugs that are eligible for discount under the Coverage Gap Discount Program. A generic drug is defined at 42 CFR 423.4 as those drug products for which there is an

4.2.4.1 Gross Drug Cost (Slide 18)

Plans must follow regulatory and sub-regulatory guidance issued by CMS when determining the total cost of the drug to report on the PDE record. For a covered drug, this cost is referred to as "gross covered drug cost" (see Module 1). The term "gross drug cost" refers to the total cost of a covered or non-covered drug on the PDE. On the PDE record, there are detail cost fields and summary cost fields that report the gross drug cost. These fields distinguish the cost of the drug itself from any dispensing fee or applicable sales tax and they identify drug costs that are eligible for reinsurance payment.

4.2.4.1.1 Detail Cost Fields

There are three detail cost fields: Ingredient Cost Paid, Dispensing Fee Paid, and Total Amount Attributed to Sales Tax. For all events, the gross drug cost is a sum total of these three detail fields in the PDE record.

Gross Drug Cost = Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax

If the PDE includes a Vaccine Administration Fee, this field will be included in the sum of gross drug cost.

4.2.4.1.2 Summary Cost Fields

For covered drugs, the gross drug cost is also represented in two summary cost fields: Gross Covered Drug Cost Below the OOP Threshold (GDCB) and Gross Covered Drug Cost Above the OOP Threshold (GDCA). These two fields distinguish costs for covered drugs that fall above or below the OOP threshold, so that covered drug costs above the OOP threshold are identified for payment under the reinsurance subsidy

For non-covered drugs, both GDCA and GDCB must be populated with a zero dollar amount ($0.00). GDCA and GDCB only track the cost of covered drugs to note their location and indicate the beneficiary's status with respect to the OOP threshold.

4.2.4.1.2.1 Gross Drug Cost Below OOP Threshold (GDCB)

The GDCB field represents the gross covered drug cost that is below or at the OOP threshold. For covered drugs, the GDCB field always has a positive dollar amount if the OOP threshold is not yet reached or if the threshold is reached during this event. Once the beneficiary exceeds the OOP threshold plans must populate the GDCB field with a zero dollar value.

4.2.4.1.2.2 Gross Drug Cost Above OOP Threshold (GDCA)

The GDCA field represents the gross covered drug cost that exceeds the OOP threshold. For covered drugs, this field is always populated with a positive dollar amount after the OOP threshold is crossed. If the threshold is reached during this event, GDCA will usually have a positive value. If the beneficiary has not reached the OOP threshold, the GDCA field will have a zero dollar value entered.

Table 4E illustrates the summary cost fields and their relationship to the TrOOP Accumulator field.

TABLE 3M – PDE RECORD LAYOUT (CONTINUED)

PDE RECORD DET – DETAIL LEVEL					
FIELD NO	**POSITION**	**SUBMISSION STATUS**	**NCPDP FIELD**	**FIELD NAME**	**EXPLANATION**
23	188 – 202	Mandatory for 2012	411-DB	Prescriber ID Number	Populate this field with either the Drug Enforcement Agency (DEA) Number or the NPI, UPIN or State License number that identifies the prescriber in cases where the DEA is not available.
24	203 – 203	Mandatory		Drug Coverage Status Code	Indicates if the dispensed drug is a Part D drug or not.
25	204 – 204	Situational		Adjustment/ Deletion Code	This field is used to identify records for either deletion or adjustment. If neither action is required the field is left blank.
26	205 – 205	Situational		Non-Standard Format Code	This field is coded only when data are collected in non-standard format. Blank indicates standard format.
27	206 – 206	Situational		Pricing Exception Code	Indicates PDEs using pricing rules that differ from the plan's negotiated price.
28	207 – 207	Optional for 2011; Mandatory prior to 2011		Catastrophic Coverage Code	Optional for PDEs with DOS January 1, 2011 and forward. Mandatory on PDEs with DOS prior to January 1, 2011. This field identifies the beneficiary's status in the benefit. It is populated when the beneficiary either reaches the OOP Threshold (code=A), or is above the OOP Threshold (code=C). This field is left blank for beneficiaries below the OOP Threshold. For any beneficiary with a "C" code in this field, there will usually be one previous record coded "A" to indicate the drug event associated with crossing the OOP threshold.
29	208 – 215	Mandatory	506-F6	Ingredient Cost Paid	Populate this field with the dollar amount paid to the pharmacy for the drug itself; do not include costs such as dispensing fees or sales tax. When costs are not disaggregated, enter the total cost of the drug in this field.
30	216 – 223	Mandatory	507-F7	Dispensing Fee Paid	Populate this field with the dollar amount paid to the pharmacy for activities related to the transfer of the drug from the pharmacy to the beneficiary. Include charges for mixing drugs, delivery, and overhead. Do not include administrative or other costs in this field.
31	224 – 231	Situational	523-FN	Amount Attributed to sales tax	This field represents the dollar amount of sales tax, if any, associated with the prescription drug event.
32	232 – 239	Mandatory		Gross Drug Costs Below Out-of-Pocket Threshold (GDCB)	Sum fields 29-31 to calculate gross drug costs. This field is populated by an actual dollar amount when the beneficiary is at or **below** the OOP threshold and the drug is a covered Part D Drug. Otherwise enter a zero dollar amount.

- DAW
- Days Supply
- Ingredient Cost Paid
- Dispensing Fee
- Amount Attributed to Sales Tax
- Prescriber ID Qualifier
- Prescriber ID

For these fields, plans may report default codes when data are unavailable. For example, the prescription service reference number is typically assigned by a pharmacy at the time a prescription is filled. However, if the drug is dispensed in a physician's office, this number may not be included on the claim so the plan will have to assign a number that is unique for the date of service and the service provider. Table 3O provides the field name and the default code or instructions directing plans to populate these fields when source data are not available.

TABLE 3O – INSTRUCTIONS FOR POPULATING THE NON-STANDARD FORMAT PDE RECORD (FOR LIMITED USE ONLY.)

FIELD NUMBER	FIELD NAME	INSTRUCTIONS
10	Prescription Service Reference Number	Assign a number that will be unique for the date of service and the service provided.
14	Service Provider ID	Utilize the UPIN, State License Number, Tax ID# or the TrOOP Facilitator Default value of "PAPERCLAIM" if an NPI is not available.
15	Fill Number	Populate with: '00'
17	Compound Code	Populate with: '0=not a compound'
18	DAW	Populate with: '0=no product selection indicated'
21	Days Supply	Populate with: '000'
22	Prescriber ID Qualifier	Populate with '99'
23	Prescriber ID	Populate with Plan defined value or 'PAPERCLAIM'
29-31	Ingredient Cost Paid; Dispensing Fee; and Amount Attributed to Sales Tax	In cases where these three fields are not disaggregated, plans should report the total cost in the "Ingredient Cost Paid" field, and report zero dollar amounts for the other two fields.

Note: The field numbers listed correspond to those included in Table 3M, which lists all fields in the PDE record.

Plans are under the same obligation to maintain an audit trail and submit accurate data independent of the data source.

TABLE 3M – PDE RECORD LAYOUT (CONTINUED)

PDE RECORD DET – DETAIL LEVEL					
FIELD NO	**POSITION**	**SUBMISSION STATUS**	**NCPDP FIELD**	**FIELD NAME**	**EXPLANATION**
23	188 – 202	Mandatory for 2012	411-DB	Prescriber ID Number	Populate this field with either the Drug Enforcement Agency (DEA) Number or the NPI, UPIN or State License number that identifies the prescriber in cases where the DEA is not available.
24	203 – 203	Mandatory		Drug Coverage Status Code	Indicates if the dispensed drug is a Part D drug or not.
25	204 – 204	Situational		Adjustment/ Deletion Code	This field is used to identify records for either deletion or adjustment. If neither action is required the field is left blank.
26	205 – 205	Situational		Non-Standard Format Code	This field is coded only when data are collected in non-standard format. Blank indicates standard format.
27	206 – 206	Situational		Pricing Exception Code	Indicates PDEs using pricing rules that differ from the plan's negotiated price.
28	207 – 207	Optional for 2011; Mandatory prior to 2011		Catastrophic Coverage Code	Optional for PDEs with DOS January 1, 2011 and forward. Mandatory on PDEs with DOS prior to January 1, 2011. This field identifies the beneficiary's status in the benefit. It is populated when the beneficiary either reaches the OOP Threshold (code=A), or is above the OOP Threshold (code=C). This field is left blank for beneficiaries below the OOP Threshold. For any beneficiary with a "C" code in this field, there will usually be one previous record coded "A" to indicate the drug event associated with crossing the OOP threshold.
29	208 – 215	Mandatory	506-F6	Ingredient Cost Paid	Populate this field with the dollar amount paid to the pharmacy for the drug itself; do not include costs such as dispensing fees or sales tax. When costs are not disaggregated, enter the total cost of the drug in this field.
30	216 – 223	Mandatory	507-F7	Dispensing Fee Paid	Populate this field with the dollar amount paid to the pharmacy for activities related to the transfer of the drug from the pharmacy to the beneficiary. Include charges for mixing drugs, delivery, and overhead. Do not include administrative or other costs in this field.
31	224 – 231	Situational	523-FN	Amount Attributed to sales tax	This field represents the dollar amount of sales tax, if any, associated with the prescription drug event.
32	232 – 239	Mandatory		Gross Drug Costs Below Out-of-Pocket Threshold (GDCB)	Sum fields 29-31 to calculate gross drug costs. This field is populated by an actual dollar amount when the beneficiary is at or **below** the OOP threshold and the drug is a covered Part D Drug. Otherwise enter a zero dollar amount.

PY 2010-2012 Duplicate Payment Approved NAIRP

Exhibit 170

From: Christopher Mucke
To: "Thomas, India M. (CMS/CPI)"
Cc: Brown, Sonja J. (CMS/CPI); Abankwah, Rosalind M. (CMS/CPI); Tetkoski, Frank (CMS/CPI); Kenya, Dominca (CMS/CPI); Brandenburg, Sara M. (CMS/CPI); Newkirk, Delois J. (CMS/CPI); Thais Thomoson
Subject: RE: Revised Duplicate Payment Decision Notice
Date: Tuesday, May 13, 2014 1:53:00 PM
Attachments: NAIRP - Duplicate Payments Final Revision CA 2.pdf
Duplicate Payments - Draft RFI.docx
Duplicate Payments - Draft RFI.pdf

India,

I have attached a copy of the Revised NAIRP, which incorporates CMS' request for a complex review. I have also attached a copy of a draft RFI that will be submitted to the SOs upon final CMS approval of the issue. Please let me know if you have any questions, Chris.

Christopher Mucke | Managing Principal | ACLR, LLC
38705 7 Mile Rd, Ste 251 | Livonia, Michigan 48152-3975 | (734) 744 - 4401 | (734) 744 - 4150 |
mailto:cmucke@aclrsbs.com

From: Thomas, India M. (CMS/CPI) [mailto:India.Thomas@cms.hhs.gov]
Sent: Tuesday, May 06, 2014 11:39 AM
To: Sean Donaghy; Christopher Mucke
Cc: Brown, Sonja J. (CMS/CPI); Abankwah, Rosalind M. (CMS/CPI); Tetkoski, Frank (CMS/CPI); Kenya, Dominca (CMS/CPI); Brandenburg, Sara M. (CMS/CPI); Newkirk, Delois J. (CMS/CPI)
Subject: Revised Duplicate Payment Decision Notice

Good Morning,

Attached is CMS' revised decision on the Duplicate Payment NAIRP. Please review and submit your updated NAIRP for final approval by COB 5/13/14. Let us know if you have any questions.

Thank you,

India M. Thomas
Health Insurance Specialist
Division of Plan Oversight & Accountability
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Mail Stop AR-18-50
410.786.1152 desk
410.922.2625 ads
410.786.0711 fax
India.Thomas@cms.hhs.gov

RECOVERY AUDIT SERVICES IN SUPPORT OF PART D
REVISED NEW AUDIT ISSUE REVIEW PACKAGE – DUPLICATE PAYMENTS

NAIRP Submission: January 2, 2014
Walkthrough Meeting: January 16, 2014
Attendees: CMS, DVC, RAC
Revised NAIRP Submission: Not Applicable
Contingent Approval: April 18, 2014
Contingent Approval - NAIRP Submission: April 25, 2014
Revised Contingent Approval: May 6, 2014
Revised Contingent Approval NAIRP Submission: May 13, 2014

REVISED CONTINGENT APPROVAL OVERVIEW:

A contingent approval of the proposed Duplicate Payment NAIRP, attached as Exhibit A, was requested to; more clearly define a duplicate payment, provide additional information regarding the 50% elapsed time approach and it application to this audit, and to provide estimated recovery amounts for each audit year in question. Upon submission of the revised NAIRP, CMS revised its contingent approval to incorporate a complex review. The revised NAIRP is outlined below.

PROCESS SUMMARY:

Duplicate payments are defined as Part D payments arising from multiple prescription drug event (PDE) submissions of a single prescription drug event. The duplicate payment review process is a complex review, which consists of an exact match review, calculating days elapsed between matched records, and calculating allowable days elapsed to identify duplicative records.

During the exact match portion of the review, we identify all plan year PDE records where the contract, beneficiary, medication, and fill number match using the PTAP_CNTRT_OF_REC, PTAP_PBP_OF_REC, PTAP_INS_CLAIM_NUM, PTAP_PROD_SERVICE_ID, PTAP_FILL_NUM fields of the PDE for open plan years. From this, PDE associated with partial fills[1] are removed as well as duplicative records associated with long term care and vaccination administrative fees[2]. In addition, duplicates arising from the transition from a retail pharmacy to a mail order pharmacy are also eliminated[3]. To mitigate and eliminate the false identification of duplicative PDE arising from the naturally recurring nature of prescriptions as well as for those arising from improper data submissions and inaccurate reporting by plans, an early fill methodology, a standard operating procedure employed by plans to improve the quality of healthcare and reduce unnecessary costs, was adopted and incorporated into a complex review. During this process, the days elapsed between two PDE selected as a result of the exact match review is determined and compared to the days supply of the originating PDE. If the days elapsed between the two PDE is less than 50%[4] of the days supply provided in the originating PDE, the subsequent PDE record is selected as potentially duplicative. An exception to this rule is applied to PDE submissions arising from non-standard sources (PTAP_NON_STAND_FMT_CD = not "Null"). These PDE

[1] *Instances where the PTAP_DISP_STAT_CD field of the PDE data = "P".*
[2] *Long term care facilities are identified by matching NPIs identified in the IDR as containing a primary, secondary, and/or tertiary code equal to "04" to the PTAP_SRVC_PROVIDER_ID field located in the PDE data.*
[3] *Mail order pharmacies are identified by matching NPIs associated with the taxonomy code 3336M0002X in NPPES to the PTAP_SRVC_PROVIDER_ID field located in the PDE data.*
[4] *Plan sponsors typically employ a 75% - 80% early fill methodology to eliminate potentially duplicative drug therapy, a 50% methodology was utilized here to maximize recoveries while minimizing the likelihood of falsely identifying duplicative PDE.*

will be subject to additional reviews to determine whether they are potentially duplicative[5]; any such records will also be selected as potentially duplicative.

Upon completion of these initial reviews, RFIs are generated and submitted to the SOs requesting detailed prescription data for all potentially duplicative PDEs[6]. To support the legitimacy of these records, SOs will be asked to submit prescriptions; override documentation due to loss, change in dosage, or other authorized override event; or other uniformly maintained readily retrievable record demonstrating the legitimacy of the potentially duplicative PDE listed in the RFI.

The RAC will review all documentation submissions received from the plans to ensure the legitimacy (non-duplicative nature) of the potentially duplicative PDE forwarded to the plans. Upon completion of its review, Improper Payment Review Packages (IPRPs)[7] will be generated from unsupported (duplicative) PDEs and forwarded to the Data Validation Contractor (DVC) for review and validation. Upon receipt of the validated records, the RAC will conduct final reconciliation, generate Notification Letters, and send to SOs for recovery of amounts owed.

Estimated Recoveries:

By incorporating our findings from the special study and applying the 50% early fill methodology to selected contracts and extrapolating the results across currently active contracts we estimate recoveries for plan years 2010, 2011, and 2012 as $36,552,276, $36,325,582, and $49,229,004, respectively.

[5] *Reviews of PDE submissions associated with non-standard format submissions are more likely duplicative, regardless of days elapsed.*
[6] *ACLR will upload all RFIs and exception reports into QuickR.*
[7] *Please see* ***Section 2.2 Validation of RAC Audit Findings*** *of Part D RAC OY1 SOW*

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS for MEDICARE & MEDICAID SERVICES
7500 Security Boulevard, Mail Stop AR-18-50
Baltimore, Maryland 21244-1850

Center for Program Integrity

Date: Date

SUBJECT: REQUEST FOR INFORMATION

CEO First Name CEO Last Name
Plan Name
Address 1
Address 2
City, State Zip Code

Re: Plan Name, Contract #

Dear CEO Prefix CEO Last Name:

The Centers for Medicare & Medicaid Services (CMS) has retained a contractor, ACLR, LLC (ACLR), to carry out the Recovery Audit Contractor (RAC) program efforts for the Medicare Part D program. The Division of Plan Oversight and Accountability (DPOA) within the Center for Program Integrity (CPI) is responsible for the Part D RAC program. The RAC program, mandated by Congress through the Affordable Care Act, is aimed at identifying and recouping improper payments made by the Medicare program

As part of our review of Prescription Drug Events (PDEs) associated with duplicate payments, we have identified PDEs, in the attached exception report, as being potentially duplicative; the originating PDEs for each of these events have also been included. Duplicative PDEs will be used as the basis for our calculation of any improper payments. In an effort to ensure the accuracy of this information, we are allowing Plan Name, Contract #, 90 calendar days from the date of this notification to submit documentation in support of or against the duplicative PDEs listed in the attached exception report.

Please submit copies of the prescriptions for both the originating and duplicative PDE; override documentation due to loss, change in dosage, or other authorized override event; or other uniformly maintained readily retrievable record to demonstrate the legitimacy of the potentially duplicative PDE listed in the RFI.

If an improper payment is determined at the conclusion of our review, a Notification of Improper Payment letter will be issued to Plan Name, Contract Number. The letter will inform you of the improper payment amount as well as appeal instructions should you disagree with our findings.

Please review the attached report and submit your response via Secure Mail to info@ACLRRAC.com within 90 days from the date of this request.

Sincerely,
ALCR, LLC
Part D National Recovery Auditor

Enclosures: Duplicate Payment Exception Report

cc: CFO: CFO Last Name, CFO First Name
MCO: MCO Last Name, MCO First Name
AM: AM Last Name, AM First Name